HFE-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

OCT 25 2000

# WARNING LETTER

**VIA FEDERAL EXPRESS**
**VIA FACSIMILE**

Mr. Richard D. Murdock
President & CEO
Kyphon, Incorporated
1350 Bordeaux Drive
Sunnyvale, California 94089

Re: Kyphon Inflatable Bone Tamp
(a.k.a. KyphyX), K981251

Dear Mr. Murdock:

The Food and Drug Administration (FDA) has reviewed your web site at the internet address: http://www.kyphon.com for the Kyphon Inflatable Bone Tamp (a.k.a. KyphyX). The Kyphon Inflatable Bone Tamp is manufactured by Kyphon, Incorporated (Kyphon) and is a device as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The Kyphon Inflatable Bone Tamp was cleared under section 510(k) of the Act and is intended to be used as a conventional bone tamp for the reduction of fractures and/or creation of a void in cancellous bone.

Your web site makes numerous intended use claims for the Kyphon Inflatable Bone Tamp, which have not been cleared by the agency. Representative examples include, but are not limited to the following: Balloon Kyphoplasty is designed to provide significant pain relief, rapid return to activities of daily living, restoration of vertebral body height, and reduction in spinal deformity. Your web site also contains pictorial representations and data from Mark Reiley, Summit Medical Center, Berkley, CA, showing vertebral height restorations, and bar graphs from Isador Lieberman, Cleveland Clinic showing improvement in pain and function. None of these claims have been cleared as part of your 510(k) submission. You also state that your inflatable balloon tamp has a low overall complication rate of less than one per cent per fracture. We believe this claim is misleading because it implies that your device is safer than those of competing manufacturers.

In one of the many testimonial statements written by Joseph Lane, Hospital for Special Surgery,

New York, Dr. Lane writes, "During Balloon Kyphoplasty, KyphyX Inflatable Bone Tamp is carefully inflated inside the vertebral body to push the collapsed bone back toward its normal position. The bone balloon also creates a space in bone that can be filled under low pressure with an appropriate material. Balloon Kyphoplasty is designed to reduce or eliminate pain, restore some or all of lost vertebral height, and to help straighten your spine. It is also designed to strengthen the vertebral body to prevent further collapse." This is essentially a description of the procedure known as vertebroplasty. Vertebroplasty is a procedure in which large spinal needles are placed into the fractured vertebral body through the pedicles, and bone cement is injected into the fractured bone. Your device, the inflatable bone tamp, is not cleared for vertebroplasty.

Promoting the Kyphon Inflatable Balloon Tamp for providing significant pain relief, rapid return to the activities of daily living, restoring vertebral body height, reducing spinal deformity, for vertebroplasty, or for claims of low overall complication rates, causes the device to be adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f), and does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a), or an approved application for investigational device exemption (IDE) under section 520(g).

The Kyphon Inflatable Bone Tamp is also misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the modification in the intended use of the device was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii), and the device was not found to be substantially equivalent to a predicate device.

This letter is not intended to be an all-inclusive list of deficiencies associated with your Kyphon Inflatable Bone Tamp. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Mr. Steven E. Budabin, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's San Francisco District Office. Please send a copy of your response to the District Director, Food and Drug Administration, San Francisco District Office, HFR-PA100, 1431 Harbor Bay Parkway, Alameda, California 94502-7070.

Sincerely yours,

Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health